K102389

JUN 10 2011

Premarket Notification 510(k) Summary
As required by section 807.92
Navigator Applications Suite

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare Finland OY
C/O Datex-Ohmeda
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-223-2496

NAME OF CONTACT:

Ms. Monica Morrison
Ms. Karla Krause (alternate)

DATE:
June 7, 2011

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Navigator Applications Suite

COMMON NAME:

Navigator Applications Suite

CLASSIFICATION NAME:

BSZ, Accessory to gas machine for anesthesia or analgesia
21 CFR 868.5160

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Navigator Applications Suite is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Navigator Applications Suite (K071097, K081941, K083098).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Navigator Applications Suite is a software product that runs on a medical grade computer and integrates information from an anesthesia delivery system, intravenous drug infusion pumps, and patient monitor. It works in a standalone or networked environment. The three main functions of the Navigator are:

- Navigator Therapy: Visualization of the modeled effect of the anesthesia drugs on the patient displayed on a point-of-care medical grade computer. The visualization is based on pharmacokinetic and pharmacodynamic (PK/PD) models and multi-drug models. Navigator also supports automatic data capture from supported intravenous drug infusion pumps and patient monitors to minimize manual data entry.
- Navigator Protocol: Framework to enable access to facility-selected care protocols at the point of care.
- Navigator Device: Electronic and interactive instructions for users to address technical issues with anesthesia delivery systems.

INTENDED USE as required by 807.92(a)(5)

Navigator Applications Suite (Navigator) is a software package that includes Navigator Therapy, Navigator Protocol and Navigator Device. Navigator software is loaded into a medical-grade PC mounted on or near the anesthesia delivery system and receives data from supported anesthesia delivery systems, anesthesia patient monitors, intravenous drug infusion pumps and/or electronic record keeping systems.

Navigator Therapy displays pharmacokinetic, pharmacodynamic (PK/PD) and interactive PD modeling information. Navigator Therapy provides the heath care professional with theoretical information about the modeled effect of supported anesthesia pharmaceuticals delivered to the patient.

The theoretical models are for the following patient populations:

Age	18 – 90 years old
Weight	40 – 140 kg / 88.2 to 308.6 pounds
Height	150 – 190cm / 59.1 to 74.8 inches

Calculated drug concentrations and effects are based on published models, and do not represent actual measurements from a patient. Drug models are calculated and displayed assuming a healthy patient. Navigator is not intended to be the sole source for patient specific guidance on clinical decisions, including dosing decisions for anesthetic drugs. Always refer to the appropriate drug labeling for dosing information and guidance.

Navigator Protocol allows hospitals to load electronic versions of care protocols. This feature can be configured with selected patient monitoring parameters available for viewing in conjunction with the care protocol.

Navigator Device is a troubleshooting aid providing access to certain anesthesia delivery system alarm information.

The system is designed for hospital use and should only be used under the orders of a clinician.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Navigator Applications Suite has been updated from the predicate version (K083098, K081941, K071097). There have been no significant changes to the intended use or fundamental scientific technology.

The Navigator Applications Suite software code has been rewritten (Version 3) with a new architecture to improve performance and user interface workflows. The Navigator Applications Suite (Version 3) is also released as a software-only product, which can be installed on any hardware (medical grade computer) meeting the minimum requirements. The previously cleared Navigator Applications Suite was shipped with mandatory hardware that was used to run the program.

Additionally, the Navigator Applications Suite Version 3 has been updated to be compatible with additional patient monitors and IV pumps.

The intended use was updated for only minor wording clarifications. The clarifications include accommodating alternate locations for the user's own medical grade computer: "...PC mounted on or near the anesthesia delivery system." Additional statements have been added to the indications for use to emphasize the theoretical and advisory nature of the device. As stated above, Navigator Version 3 software is now provided as a stand-alone product that can be ordered separately from a computer. Other minor modifications include the option for Navigator to receive data from electronic record keeping systems. In addition, imperial units (pounds and inches) were added next to the metric units for patient weight and height ranges.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Navigator Applications Suite has been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with the following standards has also been made to support safe use of the device in its intended environment.

IEC 60601-1-4: 2000	Medical Electrical Equipment, Part 4 Programmable Electrical Medical Systems

SUMMARY OF CLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(2)

The modifications made to the Navigator Applications Suite did not require clinical testing to demonstrate the safety and effectiveness of the updated device.

CONCLUSION:

The summary above demonstrates that there are no new questions of safety and effectiveness for the Navigator Applications Suite Version 3 as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

GE Healthcare Finland OY
C/O Ms. Monica Morrison
Regulatory Affairs Leader
Datex-Ohmeda, Incorporated
P.O. Box 7550
Madison, Wisconsin 53707-7550

JUN 10 2011

Re: K102389
Trade/Device Name: Navigator Applications Suite
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: May 31, 2011
Received: June 1, 2011

Dear Ms. Morrison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102389

Device Name: Navigator Applications Suite

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Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102389